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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,617	06/07/2000	NIGEL J. FORROW	6237.US.01	8065

7590 03/03/2003

STEVEN F WEINSTOCK
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
D 377 AP6D
ABBOTT PARK, IL 60064-6050

EXAMINER

OLSEN, KAJ K

ART UNIT

PAPER NUMBER

1753

DATE MAILED: 03/03/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,617

Applicant(s)

FORROW ET AL

Examiner

Kaj Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-11 and 16-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-11 and 16-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 18-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 18 sets forth an electrode strip comprising a mediator compound where R1 has a nitrogen in the 1-position and R2 has a nitrogen in the 8-position. The examiner cannot find any support for this specific form of R1 and R2. The cited portions of the specification identified by the applicant only broadly defined elements of R1 and R2 (which included pyridyl units so support exists for the use of six-member heteroaromatic rings). There does not appear to be anything in the originally filed disclosure about the specific use of heteraromatics with nitrogens specifically in the 1-position and the 8-position. Moreover, there does not appear to be anything in the originally filed disclosure concerning the specific molecules of claims 19 and 26. Clarification is requested.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 18-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 18 specifies that R2 has a nitrogen in the 8-position. However, the structure shown in claims 19 and 26 show the nitrogen in the 9-position, not the 8-position. Applicant might be relying on the atom numbering scheme typically utilized for similar molecules like anthracene (in that case, the nitrogen of claims 19 and 26 would be the 8-position). However, naming convention for the molecule of claims 19 and 26 does not support this numbering system. This was evidenced by Chemical Abstract Service (CAS), which identified the molecule of claims 19 and 26 as being a "5,10-dione" (and not a "9,10-dione" if anthracene number were appropriate). Clarification is requested.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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3. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hedenmo et al (Analyst, 1996, vol. 121, pp. 1891-1895) in view of Carter et al (USP 5,628,890). Hedenmo is being cited and utilized for the first time with this office action.

4. Hedenmo discloses a sensor that comprises an active electrode comprising a nicotinamide co-factor dependent enzyme glucose dehydrogenase (GDH), a cofactor of nicotinamide adenine dinucleotide (NAD/NADH), and a mediator containing the molecule 1,10-phenanthroline 5, 6-dione that reads on the claimed formulae (fig. 1). Said electrode is also constructed with filler (carbon) and binder (paraffin oil) ingredients (see "Preparation of Carbon Paste Electrodes", p. 1892). Hedenmo does not explicitly recite the use of the various supports, conductive tracks with reference and counter electrodes, all these specified elements are conventional aspects of electrode strip construction that are to be used with readout circuitry. Carter shows a protocol for constructing strip sensors and provides a sensor where the location of the sample delivery can be controlled making the sensor easy for an unskilled user to manipulate (see fig. 1 and the associated discussion therein). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Carter for the sensor of Hedenmo because the protocol of Carter is conventional in the art and provides a sensor that is easy for the user to manipulate.

5. Claims 4, 5, 7-11 are rejected under 35 U.S.C. 103(a) as obvious over Hedenmo and Carter as applied to claim 1 above, in further view of Batchelor.

6. With respect to claim 4, the references set forth the limitations of the claim, and Hedenmo further identified that the NAD acts as a coenzyme for over 300 dehydrogenases (see Introduction) but did not explicitly identify the use of HBDH as the cofactor-dependent enzyme.

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Batchelor teaches an analogous sensor which utilizes the enzyme 3-hydroxybutyrate dehydrogenase which is thereby capable of measuring 3-hydroxybutyrate (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Batchelor for the sensor of Hedenmo and Carter in order to extend the utility of the sensor of Hedenmo to additional compounds such as 3-hydroxybutyrate.

7. With respect to the claims drawn to the method of using the electrode of claim 1 (those limitations not already discussed above), Hedenmo set forth the various components of the sensor and teaches how the various components interact to provide the sensor (fig. 1), but did not explicitly disclose the use of NAD(P). Batchelor teaches in an alternate electrochemical assay that NAD(P) is an alternate form of nicotinamide that finds equivalent utility in the art to that of NAD (p. 289). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Batchelor for the sensor of Hedenmo and Carter because the substitution of one known nicotinamide for another when the results are not unexpected requires only routine skill in the art.

8. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hedenmo and Carter as applied to claim 1 above, and further in view of Hilt et al (Chemistry, A European Journal, 1997, vol. 3(1), pp. 79-88). Hilt is being cited and relied on for the first time with this office action.

9. Hedenmo and Carter set forth all the limitations of the claim 16 but did not explicitly recite the presence of an alkyl substituted R1 and/or R2 group. With respect to claim 17, Hedenmo and Carter did not explicitly set forth where R1 and R2 are unsubstituted (Hedenmo is complexed with Os which the examiner is construing as constituting a substitution). Hilt teaches

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that the use of the uncomplexed form of 1,10-phenanthroline-5,6-dione (PD) as well as a alkyl substituted version of PD were known variants of the PD complexes like those of Hedenmo (see introduction and Scheme 1). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Hilt for the sensor of Hedenmo in view of Carter because the substitution of one known form of a particular dione for another when the results are not unexpected requires only routine skill in the art.

Allowable Subject Matter

10. With respect to claims 18-29, the prior art does not disclose a disposable electrode strip comprising a mediator having the set forth formula having the specified R1 and R2 groups comprise six-membered heteroaromatic rings having nitrogens in the set forth positions. The closest prior art is Itoh, which teaches a molecule that reads on the claimed formula (fig. 1, molecule 7). However, Itoh is drawn to "[e]nzymatic catalysis in organic synthesis" (see introduction) and not sensor strips as set forth by the claims.

Response to Arguments

11. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The

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examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for regular communications is (703) 305-3599 and the fax number for after-final communications is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.



Kaj K. Olsen
Patent Examiner
AU 1753
February 27, 2003